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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,773	03/30/2001	Robert F. Hofmann	TORQ-0002 (103336.00004)	6970
7590 11/17/2003			EXAMINER PAK, JOHN D	
T. Ling Chwang Jackson Walker L.L.P. Suite 600 2435 N. Central Expressway Richardson, TX 75080			ART UNIT PAPER NUMBER 1616 12	
DATE MAILED: 11/17/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/822,773

Applicant(s)

HOFMANN ET AL.

Examiner

JOHN D PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Claims 1-55 are pending in this application.

Claims 1-23 and 25-28 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons fully stated in the previous Office Action, Paper No. 9, the paragraph bridging pages 2 and 3.

Claims 1-23 and 25-28 are readable on "an aromatic redox compound" with no further clarification. The Examiner's position was fully set forth in the previous Office Action. Applicant replies that aromatic redox compounds are disclosed on page 12, lines 10-15 of the specification. The Examiner finds the disclosure there insufficient. The Examiner specifically asked in the previous Office Action, "Besides the quinones that are disclosed in the specification and other claims, what else is covered by this term?" Applicant failed to answer this question. The specification states that the aromatic redox compounds "includes" substituted or unsubstituted benzoquinones, naphthoquinones or anthroquinones. The Examiner notes that the term "includes" does not give further guidance as to what else may be encompassed. This has been the Examiner's position of record. The term "redox" refers to a reaction that involves the transfer of electron between two chemicals. A compound can be an electron donating or accepting substance depending on the conditions. Therefore, it is not understood what is meant by "an aromatic redox compound" in the present context, i.e. as a component of a system that contains peroxidic species or oxidized alkenes, solvent,

dye, and electron donors for treating arteriosclerosis. This ground of rejection must therefore be maintained.

Claims 1-55 stand rejected for the reasons of record under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific compositional ingredients and percentages shown on specification pages 15 and 16 (Examples 3A and 3B), does not reasonably provide enablement for the more broadly claimed subject matter, including those without specific percentages for components. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's arguments have been given due consideration, but they were deemed unpersuasive. Arguments as to anticipation or obviousness are misdirected under this ground of rejection based on lack of enablement for the entire scope of the claimed subject matter. The Examiner has shown, in the previous Office Action, through analysis of each Wands factors that one skilled in the art would be faced with undue experimentation to use the invention to the full extent claimed. Full discussion from said Office Action is incorporated herein by reference. See Paper No. 9, from last paragraph on page 3 to end of the first paragraph on page 5.

For further clarification, it is noted that the composition and the method are directed to treating patients with coronary diseases. The claims are wide open as to any amounts of any of the recited ingredients, whereas the specification examples were obtained with 98% DMSO (solvent), 0.83% hematoporphyrin, 0.24% methyl

naphthoquinone, and 0.39% dye. Such a disparity between the scope of the claims and the guidance and working examples provided in the specification makes the state of the art even more difficult to resolve in applicant's favor. Chemical Abstracts 125:9418 and 105:223647 have been cited to show that components of applicant's invention can have individual roles in atherogenesis and blocking the cardiovascular benefit of another agent, respectively, i.e. effects that may be detrimental to treating coronary diseases. For these reasons and for the reasons of record, the Examiner finds that the entire scope of the claims, which is without any limitation as to percentages and proportions, is not adequately enabled; and one skilled in the art would not be able to use or practice the claimed invention to the full extent claimed (i.e. open percentages and proportions, "aromatic redox compound") without undue experimentation, keeping in mind the high risk of unacceptable consequences associated with treating coronary disease conditions.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN D PAK whose telephone number is (703)308-4538. The examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.



**JOHN PAK**  
**PRIMARY EXAMINER**  
**GROUP 1600**